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Supreme Court of the United States

OCTOBER TERM, 1984

R. ANTHONY MARRESE, M.D. and BONE AND JOINT SURGEONS, INC.,

Petitioners,

v.

INTERQUAL, INC., et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Did the Seventh Circuit Court of Appeals establish any new standards for the determination of state action immunity from the federal antitrust laws?

2. Did the Seventh Circuit Court of Appeals establish any conflict among the circuits as to the standards to be applied in determining whether a state's program qualifies for state action immunity from the federal antitrust laws.

3. Does Indiana's statutory program governing hospitals and physicians which requires hospitals and their medical staffs to conduct peer review concerning the quality and necessity of medical care, provides for absolute immunity from civil liability for good faith participants in such review and supervises its implementation through both administrative regulation and judicial proceedings qualify for exemption from the federal antitrust laws under the state action immunity doctrine?

ADDITIONAL STATUTES AND REGULATIONS INVOLVED

Ind. Code §§ 16-10-1-7; Ind. Code § 16-10-1-9; Ind. Code § 16-10-1-12; Ind. Code § 16-10-1-13; Ind. Code § 16-10-1-14; Ind. Code § 16-10-17; 410 Ind. Adm. Code 15-1-1; 410 Ind. Adm. Code 15-1-2; 410 Ind. Adm. Code 15-1-5; 410 Ind. Adm. Code 15-1-7; 410 Ind. Adm. Code 15-1-8 and §44 Ind. Adm. Code 4-6-1 to 4-6-10.

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SUPPLEMENTAL STATEMENT OF THE CASE

This case involves a challenge under Federal Anti Trust Laws to revocation of Petitioner's privileges at Deaconess Hospital. The revocation occured after a peer review hearing held pursuant to a Fair Hearing Plan required by the State of Indiana.

The Petitioners originally filed this lawsuit in the summer of 1982. The complaint alleged violations of the Sherman Antitrust Act and requested an injunction against the Respondents barring them from proceeding with the "fair hearing proceeding" which was then pending. Respondents questioned *inter alia* whether the state action exemption applied to this case. The District Court dismissed Petitioner's lawsuit in February of 1983 on jurisdictional grounds, and did not reach the state action exemption issue. During the pendency of the

matter in the Seventh Circuit Court of Appeals, supplemental briefs were requested by the court on the state action exemption issue for medical staff peer review. Such briefs were filed, and the court issued its decision in November of 1984.

During the pendency of the matter in the District Court, the peer review hearing did not proceed. The matter was set for a hearing on the plaintiff's medical staff privileges after the case was dismissed.

There is substantial material in the petition and appendix which is outside the record. The actual record before the court consists of the pleadings and rulings thereon. The Complaint alleges that Dr. Marrese is an orthopedic surgeon who was practicing alone as Bone and Joint Surgeons, Inc. in Evansville, Indiana. When the matter was originally filed, he had surgical privileges at Deaconess Hospital, one of the hospitals in that community. The hospital had adopted a "Fair Hearing Plan" which provided procedures for hearing and decision regarding the nature and extent of hospital staff privileges for any physician whose privileges came into question. The complaint further alleges that the "peer review committee" established thereunder was authorized pursuant to Indiana Statute. Dr. Marrese filed suit in the District Court naming the participants in the peer review process as defendants. These included those persons who had previously been designated as prospective members of the peer review committee as well as members of the Board of Directors of the hospital, the administrator of the hospital, the attorney for the hospital and an outside medical audit company.

Prior to the hearing scheduled before the peer review committee, but subsequent to the dismissal of this case by the District Court, Dr. Marrese filed a verified complaint for injunction in the Vandenburgh Circuit Court of the State of Indiana, Cause No. 9454, challenging the peer review proceeding, the composition of the review panel and the good faith of the participants in the peer review procedure.

Dr. Marrese was offered an alternative panel of physicians associated with Indiana University Medical School and completely outside of Deaconess Hospital (and indeed Evansville, Indiana) for his peer review panel which he declined. He raised objections to a specific panel member at the time of hearing on his complaint for preliminary injunction, and that panel member was voluntarily withdrawn by the hospital. An evidentiary hearing was held before Judge William H. Miller, regular judge of the Vandenburgh Circuit Court on July 8, 1983. At the conclusion of that hearing Judge Miller made the following ruling:

> "Let the record show that the court finds that Peer Review Statute covers this procedure that the petitioner attacked, petitioner being the plaintiff and now finds the plaintiff having failed to prove malice on the part of the amended panel, the court now OVERRULES plaintiff's Motion For Temporary Restraining Order, Preliminary Injunction." (Transcript of hearing, pages 113-114)

As acknowledged in Petitioner's Appendix, he unsuccessfully appealed that order to both the Indiana Court of Appeals and the Supreme Court of the State of Indiana.

After the State Court denied Dr. Marrese's request for an injunction, the peer review committee met for two days and heard over 600 pages of testimony. The parties were represented by counsel and were granted the right to voir dire of the members of the panel, all of whom were physicians on the medical staff of Deaconess Hospital. After voir dire, Mr. Sharpe, counsel for Dr. Marrese, made the following statement on the record:

> "Mr. Powell, we have no objections to the members of the Hearing Panel, we think they are taking their position here quite seriously and it seems to us that they are going to make an effort to give an objective hearing today." (Transcript of Fair Hearing, Pg 15)

In addition to being given the right of voir dire, the parties had opportunity to present evidence and cross examine opposing witnesses as well as the right to make opening and closing statements. Subsequent to the hearing, the panel made and presented written findings which included a recommendation that Dr. Marrese's staff privileges be terminated. An appeal was taken to the hospital's Board of Directors which ratified the action of the hospital's peer review committee.

Respondents readily concede that much of this is outside of the record before this Court-as is much of Petitioners' statement of the nature of this case. It is brought to the court's attention because the Respondents believe that the Petitioner's version of the events which have occurred is substantially misleading and incomplete.

NATURE OF THE CASE

This petition is before this court on the limited issue of whether the Indiana statutory and regulatory program exempts medical staff peer review proceedings from federal antitrust laws. The Indiana Code contains three titles enacted by the legislature which apply to this situation. Title 16 of the Indiana Code deals with Health and Hospitals, Title 25 deals with Medical Licensing, and Title 34 contains Special Provisions Relative to Peer Review. Indiana has also published regulations adopted pursuant to Statute in the Indiana Administrative Code.

I.
INDIANA STATUTORY AND REGULATORY SCHEME

A. SUMMARY OF INDIANA LEGISLATIVE STRUCTURE

Under Indiana law, a hospital and its medical staff are required to engage in medical quality peer review. Specific statutory provisions set forth the parameters of peer review and

minimum requirements for its implementation. All physicians are required to have their hospital privileges reviewed at least every 2 years, and a hospital is required to immediately report any non-compliance with the statutory requirements which include peer review. A Hospital Licensing Council is empowered to suspend or revoke a hospital's license, or, in the alternative, allow it to continue operating temporarily if that does not injure patient health, safety and welfare. Hospitals are required to be inspected regularly, and hospital licenses are renewed annually.

The Indiana legislature provided for immunities for those engaged in peer review. The State of Indiana has clearly determined that peer review is necessary and required. It has further determined that it should be initiated by hospitals and their medical staffs who are in a position to have both the knowledge and expertise to intervene to protect the public health, safety and welfare. Broad immunities have been granted to ensure the willingness of the participants to engage in a review of another physician's standards of practice. Limited judicial review is provided under standards set by the Indiana legislature.

B. HOSPITAL LICENSING

Hospitals are licensed and regulated by the Indiana State Board of Health. Indiana Code § 16-10-1-1 through § 16-10-1-19. The State Board of Health administers the hospital licensing statute with the advice and consent of a Council created pursuant to statute. Ind. Code § 16-10-1-3 and § 16-10-1-4. The Hospital Council consists of 8 members appointed by the state's governor. The governor is directed to appoint a physician, a registered nurse, four hospital administrators and two additional members from the State Department of Public Welfare and the State Board of Health. Ind. Code § 16-10-1-3.

The legislature defines a hospital for purposes of state regulation in Indiana Code § 16-10-1-6. The plaintiff alleges,

and there is no dispute, that Deaconess Hospital is a hospital pursuant to statute.

Hospitals are required to have a Governing Board which is statutorily defined and granted the following authority:

> "(a) The governing board of the hospital shall be the supreme authority in the hospital responsible for the management, operation, functioning, and control of the hospital, and the appointment of the members of the medical staff and the assignment of privileges to members of the medical staff with the advice and recommendations of the medical staff consistent with their individual training, experience and other qualifications.
>
> (b) The governing board shall report, in writing, to the Indiana medical licensing board, the results and circumstances of any final, substantive, and adverse disciplinary action taken by the governing board regarding a physician on the medical staff, or an applicant for the medical staff, if the action results in voluntary or involuntary resignation, termination, nonappointment, revocation, or significant reduction of clinical privileges or staff membership. . . .The governing board and its employees, agents, consultants and attorneys have absolute immunity from civil liability for communications, discussions, actions taken, and reports made concerning disciplinary action or investigation taken or contemplated, if such reports or actions are made in good faith and without malice." Ind. Code § 16-10-1-6.5.

The same statutory provision provides for certain responsibilities of the medical staff as follows:

> "(c) The medical staff of a hospital shall be an organized group which shall be responsible to the governing board for the clinical and scientific work of the hospital, advice regarding professional matters and policies to the governing board, and shall have the responsibility of reviewing the professional practices in the hospital for the purpose of reducing morbidity and mortality, and for the improvement of the care of patients in the hospital. This review shall include, but shall not be limited to, the quality and

necessity of the care provided patients and the preventability of complications and deaths occurring in the hospital.

(d) The members of any medical staff committee organized for the purpose of conducting medical review, being retrospective and not a part of current patient care, shall have an absolute immunity from civil liability for communications made in committee meetings, and reports and recommendations made by the committee arising from deliberations by the committee to the governing board of the hospital or another duly authorized medical staff committee." Ind. Code § 16-10-1-6.5.

Hospitals in Indiana are required to be licensed. Indiana Code § 16-10-1-7. Application for a license is submitted to the Hospital Council which is granted authority to conduct investigations and hold hearings. Licenses, when granted, are issued for a period of one year and are subject to annual renewal. Ind. Code § 16-10-1-9. The State Board of Health is granted authority to suspend or revoke a hospital license pursuant to the terms of Ind. Code § 16-10-1-10. The grounds set forth in the statute include violation of any provision of the chapter relating to licensing or any rule or regulation issued thereunder. Grounds for revocation or suspension can also include conduct or practice found by the Council to be detrimental to the welfare of the patients in such institution. The Council is granted authority to adopt rules and regulations as are necessary in the public interest. Ind. Code § 16-10-1-12. The State Board of Health is required to periodically inspect any hospital licensed in the State of Indiana pursuant to the statutes and rules and regulations adopted and approved by the Council and the Board. Ind. Codes §§ 16-10-1-13 and 16-10-1-14.

A number of regulations have been adopted by the Indiana State Board of Health pursuant to its statutory authorization. The regulations relevant to hospital operation and management are found primarily at 410 Ind. Adm. Code (IAC) § 15-1-1 through § 15-1-23. Hospitals, as a condition for maintaining their license, are required to comply with all regulations. 410 IAC 15-1-2. In addition, if a situation arises

which prevents a hospital from complying with any regulation, the hospital is required to report that to the Hospital Licensing Council. The Council may, under those circumstances, permit the hospital to continue operation for a specified period of time if compliance is not immediately possible and the safety and well being of patients will not be jeopardized. 410 IAC 15-1-2.

The hospital governing board is required to file an annual application for licensing. It is required to adopt by-laws by which the hospital will function. It is also required to approve by-laws, rules and regulations of the medical staff and audit procedures or other measures used to assure quality of care. The hospital governing board has the responsibility to appoint members to the medical staff and assign them privileges. The assignment is not permanent but is granted on a periodic basis with renewal terms not to exceed two years. Privileges are granted with the advice and recommendations of the medical staff. 410 IAC 15-1-5.

The medical staff is required to initiate, adopt and amend by-laws, rules, regulations and policies including those relating to qualifications for appointment to staff membership and for deliniation of privileges. 410 IAC 15-1-7(2). These rules are to be submitted to the governing body of the hospital for approval. The medical staff is specifically required to include provisions for:

> "(d) Establishment of mechanism to carry out Medical Staff functions either by the staff as a whole or by designated committees in the following areas:
>
> (1) Review of applications for staff membership, deliniation of privileges, and recommendation on appointment to the Governing Body.
>
> (2) Appeal of decisions regarding Medical Staff membership and privileges.
>
> (3) Review and analysis, at regular stated intervals, of clinical performance, pathological reports, the completeness of medical records and the enforcement of requirements related thereto, of infection control, of use of blood and blood related elements, and of total patient care." 410 IAC 15-1-7(2)(d).

The hospital is specifically required to maintain a number of records for inspection (and forwarding if requested) by the Hospital Licensing Council and the State Board of Health. These records include the constitution, by-laws, rules and regulations of the Governing Body and Medical Staff; the minutes of meetings of the Governing Body, the Medical Staff and committees thereof and the privileges of all members of the Medical Staff. 410 IAC 15-1-8.

C. MEDICAL LICENSING

The legislature created a Medical Licensing Board to govern and regulate the conduct of physicians. Ind. Code § 25-22.5-2-1 *et seq.* The governor appoints 7 persons who make up the Medical Licensing Board consisting of 5 physicians, an osteopathic physician and a member of the general public. The Medical Licensing Board meets a minimum of two times each year and more often if necessary. A service bureau is established to keep records, including applications, licenses and permits. Ind. Code § 25-22.5-2-2.

The legislature has set forth statutory requirements for the licensing of physicians as well as guidelines on the examinations administered to applicants. Ind. Code §§ 25-22.5-3-1 and 25-22.5-4-1.

The legislature also granted the Board the power to promulgate rules and regulations relating to medical licensing. Ind. Code § 25-22.5-2-7. The Medical Licensing Board is granted the power to enforce all provisions of the Indiana Medical Licensing Statute and also assign the service bureau duties necessary for the enforcement of the statute. Ind. Code § 25-22.5-2-7.

A licensed physician in Indiana must conduct his practice in accordance with the standards established by Medical Licensing Board. Ind. Code § 25-22.5-6-2.1(b). The Indiana legislature has provided for the method of initiating potential

sanctions against a physician. Any person who initiates or participates in any proceedings for sanctions is immune from civil liability. Ind. Code § 25-22.5-6-3. The Medical Licensing Board receives required reports from hospitals regarding adverse disciplinary actions taken against any of their staff physicians. Ind. Code 25-22.5-6-3 and 16-10-1-6.5. The Licensing Board's actions are, thereafter, independent of any proceedings previously taken by a hospital staff pursuant to the required peer review procedures.

D. PEER REVIEW

The Indiana legislature has further codified requirements, standards and procedures for peer review committees under Chapter 12.6 Title 34 of the Indiana Code. Definitions are provided under Ind. Code § 34-4-12.6-1. Under subsection (c) thereof, a "peer review committee" means a committee having the responsibility of evaluation of qualification of health care providers or of patient care rendered by health care providers. The criteria for composition of the committee is set out in the statute. These include committees organized by a professional staff of a hospital or a governing board of a hospital. A physician is included in the definition of professional health care provider and is subject to the evaluation of patient care set forth in the Indiana Code. Evaluation of patient care includes:

> "(2) The propriety, appropriateness, or necessity of care rendered by a professional health care provider; and
>
> (3) The reasonableness of the utilization of services, procedures and facilities in the treatment of individual patients. Ind. Code § 34-4-12.6-1(b).

Further definitions state:

> "(e) As used in this chapter 'personnel of a peer review committee' means not only members of the committee but also all of the committee's employees, representatives, agents, attorneys, investigators, assistants, clerks, staff, and any other person or organization who serves a peer review committee in any capacity.

> (f) As used in this chapter 'in good faith' refers to an act taken without malice after a reasonable effort to obtain the facts of the matter and in the reasonable belief that the action taken is warranted by the facts known. In all actions to which this chapter applies, good faith shall be presumed; and malice shall be required to be proven by the person aggrieved." Ind. Code § 34-4-12.6-1.

A professional health care provider under investigation is provided certain procedural rights and privileges pursuant to statute. These include the right to see any records accumulated by a peer review committee pertaining to his practice and to appear before the committee with representation to hear all charges and findings and to offer rebuttal information. The statute provides for one evidentiary hearing before the peer review committee of the medical staff and one appellate hearing before the governing board of the hospital. Ind. Code § 34-4-12.6-2.

The legislature provided protection for the participants in the peer review procedure proceedings.

> "Immunity—(a) There shall be no liability on the part of, and no action of any nature shall arise against, the personnel of a peer review committee for any act, statement made in the confines of the committee or proceeding thereof made in good faith in regard to evaluation of patient care as that term is defined and limited in section 1(b) of this chapter." Ind. Code § 34-4-12.6-3.

As indicated earlier, good faith, by statute, is presumed, and malice is required to be proven. Ind. Code § 34-4-12.6-1(f).

REASONS FOR DENYING THE WRIT

1. INDIANA'S LEGISLATIVE PROGRAM REQUIRING PEER REVIEW IS A CLEARLY ARTICULATED AND AFFIRMATIVELY EXPRESSED STATE POLICY MEETING ALL REQUIREMENTS FOR THE PARKER EXEMPTION FROM FEDERAL ANTITRUST LAWS.

A. PARKER DOCTRINE

This Court in *Parker v. Brown,* 317 U.S. 341, 87 L.Ed. 315, 63 S.Ct. 307 (1943), first articulated the state action doctrine under the Sherman Antitrust Act. It is based on the dual sovereignty of the federal and state governments. This Court indicated that, pursuant to the supremacy clause, there are areas where Congress can nullify state actions. However, the court also articulated the rule that an unexpressed intention by Congress to overrule a state statute would not be lightly inferred.

In *Parker,* California adopted a "marketing program" for the 1940 raisin crop which restricted competition among growers and maintained price levels in the distribution of raisins from the growers to the packers. The California legislature's declared purpose was to conserve the agricultural wealth of California and to prevent economic waste in the marketing of agricultural products. This Court construed the program's authority as being derived from the legislative command of the state and assumed that the program would violate the Sherman Act if done without state involvement. It further assumed that Congress had constitutional authority to prohibit this state program. The state's purpose was presumed to restrict competition among growers and to maintain prices of agricultural commodities. A state commission was appointed by the governor. A committee selected from among the growers was to formulate and administer the program subject to the approval of the Director of Agriculture. The court set forth the policy considerations for this doctrine as follows:

"We find nothing in the language of the Sherman Act or in its history which suggests that its purpose was to restrain a state or its officers or agents from activities by its legislature. In a dual system of government in which, under the Constitution, the states are sovereign, save only as Congress may constitutionally subtract from their authority, an unexpressed purpose to nullify a state's control over its officers and agents is not lightly to be attributed to Congress." Id. at 350, 351

B. THE STATE MUST IN FACT HAVE ACTED

In *Goldfarb v. Virginia State Bar,* 421 U.S. 773, 44 L.Ed. 2d 572, 95 S.Ct. 2004 (1975) the court found that a minimum fee schedule published by the Fairfax County Bar Association was price fixing subject to Sherman Act proscription. The court first noted that attorneys are subject to regulation by the Supreme Court of the state, here Virginia. It further noted that the state bar was, for some purposes, a state agency, although the Fairfax County Bar Association was, in all respects, a private party. The court further noted that the Virginia Supreme Court had adopted ethical codes dealing with fees which explicitly directed attorneys not to be controlled by fee schedules. The fee schedule was initially promulgated by the state bar which apparently had authority in Virginia to act as an administrative agency of the court in investigating and reporting violation of rules and regulations adopted by the court.

The Supreme Court indicated:

"The threshold inquiry in determining if an anticompetitive activity is state action of the type the Sherman Act was not meant to proscribe is whether the activity is required by the state acting as sovereign. (citations omitted). Here we need not inquire further into the state action question because it cannot fairly be said that the state of Virginia through its Supreme Court rules required the anticompetitive activities of either respondent. Respondents have pointed to no Virginia statute requiring their activities; state law simply does not refer to fees,

leaving regulation of the profession to the Virginia Supreme Court . . . ." Id at 790

The court observed that the state bar did not have the authority to act as sovereign and that the state Supreme Court had not so acted. It is clear that if the sovereign had acted, that action would not be barred by the Sherman Act. Further the court was careful to note the state interest in the regulation of professions and stated as follows:

> "We recognize that the states have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions. We also recognize that in some instances the State may decide that 'forms of competition usual in the business world may be demoralizing to the ethical standards of a profession' . . .
>
> In holding that certain anticompetitive conduct by lawyers is within the reach of the Sherman Act, we intend no diminution of the authority of the State to regulate its professions." Id. at 792, 793

Unlike *Goldfarb,* we have a situation wherein the state legislature, as sovereign, has required that peer review committees be formed and that they review and evaluate the privileges of physicians on hospital staffs. Under Indiana law, a hospital and its medical staff must establish and implement peer review.

C. COMPULSION IS NOT REQUIRED

The Petitioner originally relied on the case of *United States v. Southern Motor Carriers Rate Conference,* 702 Fed. 2d 535 (5th Cir. 1983). As this court is aware, the Fifth Circuit had held that private parties would be immune from federal antitrust liability only if the state compelled the specific anticompetitive conduct at issue. This court reversed the Fifth Circuit in *Southern Motor Carriers Rate Conference, Inc., et al.*

v. United States, ____ U.S. ____, 82-1922 (March 27, 1985), 53 L.W. 4422. Prior to this court's decision, Petitioner contended that there was a conflict or ambiguity among the circuits regarding this issue. Obviously, it has now been resolved. This court ruled that:

> "The *Midcal* test does not expressly provide that the actions of a private party must be compelled by a state in order to be protected from the federal antitrust laws." Id. at 4424
>
> "Moreover, a state policy that expressly *pemits,* but does not compel, anticompetitive conduct may be 'clearly articulated' within the meaning of *Midcal.* Our holding today does not suggest, however, that compulsion is irrelevant. To the contrary, compulsion often is the best evidence that the state has a clearly articulated and affirmatively expressed policy to displace competition." Id. at 4425
>
> "Parker immunity is available only when the challenged activity is undertaken pursuant to a clearly articulated policy of the state itself, such as the policy approved by a state legislature . . . . " Id. at 4426

D. INDIANA'S STATUTES COVER PEER REVIEW

Under the standards set forth by this court, we now look to the legislative and regulatory program adopted by the State of Indiana to ascertain whether the Seventh Circuit erred in its determination that "the State of Indiana has 'clearly articulated and affirmatively expressed the state policy' that hospital medical staffs are to form peer review committees and that such committees are to review the quality and necessity of the care provided patients, to evaluate the qualifications of staff members, and review the merits of any recommendation against a staff member." *Marrese v. Interqual,* 748 Fed. 2d 373 (7th Cir. 1984).

The Petitioner contends that the Seventh Circuit opinion is based on a generalized theory that pervasive regulation of a profession is evidence of the legislature's intent to displace

competition. The question is much narrower—is Indiana's regulation of peer review state action under the *Parker* doctrine? It is true that Indiana has extensive regulation of the medical profession and of hospitals. However, Respondents do not contend that any action by a professional is automatically exempt from federal antitrust laws because of that state regulation. No fair reading of the opinion in this case could leave the impression that the Seventh Circuit based its decision on generalized regulation. The contentions involved in this case are quite specific. Dr. Marrese has challenged the Respondents' conduct and motives as participants in the medical peer review proceeding at Deaconess Hospital involving Dr. Marrese.

There can be little question that Indiana has, through its legislature, established policies regarding peer review requirements of hospitals. Included in the statutory requirements placed upon hospitals are that the governing board of the hospital *shall* be responsible for the appointment of members of the medical staff and the assignment of privileges to the members of the medical staff with the advice and recommendations of the medical staff. The medical staff *shall* have the responsibility of reviewing the professional practices in the hospital, and the review *shall* include the quality and necessity of care provided patients. Ind. Code § 16-10-1-6.5.

Pursuant to regulations adopted by the Indiana State Board of Health, a state agency, the governing body of the hospital is *required* to adopt by-laws by which the hospital will function, to approve rules and regulations of the medical staff (including audit procedures to assure quality of care) and to appoint the members of the medical staff and assign privileges. The regulations also *require* that the medical staff review the professional practices in the hospital. The medical staff, with the approval of a hospital governing board, is required to adopt by-laws, rules and regulations, including provisions for appointment to staff membership and delineation of privileges. All of these documents are to be reviewed by the State Board of

Health. 410 IAC 15-1-1 et seq. The State Board is required to periodically inspect hospitals to be sure that they continue to comply with state requirements. Ind. Code § 16-10-1-13. Hospital licenses are issued for a period of one year and are subject to suspension or revocation if the hospital violates any of the provisions of the legislative scheme and the rules and regulations adopted pursuant thereto. Ind. Code § 16-10-1-9 and § 16-10-1-10; 410 IAC 15-1-2.

The Indiana legislature has specifically provided for peer review and required that hospitals and their medical staff must undertake medical peer review which includes the quality and necessity of care provided to patients. Ind. Code § 16-10-1-6.5. In this same section, the legislature also provides:

> "The members of any medical staff committee organized for the purpose of conducting medical review, being retrospective and not a part of current patient care, shall have an absolute immunity from civil liability for communications made in committee meetings, and reports and recommendations made by the committee arising from deliberations by the committee to the governing board of the hospital or another dul authorized medical staff committee." Ind. Code § 16-10-1-6.5 (d)

E. INDIANA'S STATUTES PROVIDE FOR IMMUNITY

The legislature also enacted a separate chapter providing immunity for peer review committees. Ind. Code § 34-4-12.6-1 et. seq. A peer review committee is statutorily defined and includes all of the defendants herein. Ind. Code § 34-4-12.6-1. The legislature then provides immunity as follows:

> "*Immunity*-(a) There shall be no liability on the part of, and no action of any nature shall arise against, the personnel of a peer review committee for any act, statement made in the confines of the committee, or proceeding thereof made in good faith in regard to evaluation of patient care as that term is defined and limited in Section 1(b) of this chapter." Ind. Code § 34-4-12.6-3(a)

It defines good faith as follows:

> "(f) As used in this chapter, 'in good faith' refers to an act taken without malice after a reasonable effort to obtain the facts of the matter and in the reasonable belief that the action taken is warranted by the facts known. In all actions to which this chapter applies, good faith shall be presumed; and malice shall be required to be proven by the person aggrieved." Ind. Code § 34-4-12.6-2(f)

The legislature provided that a physician whose privileges were under question would be "entitled to only one (1) evidentiary hearing before a peer review committee of the medical staff and one (1) additional hearing on appeal before the governing board of the hospital." Ind. Code 34-4-12.6-2(b)

The state legislature then further goes on to require

> "(b) The governing board shall report, in writing, to the Indiana Medical Licensing Board the results and circumstances of any final, substantive, and adverse disciplinary action taken by the governing board regarding a position on the medical staff, or an applicant for the medical staff, if the action results in voluntary of involuntary resignation, termination, non appointment, revocation, or significant reduction of clinical privileges of staff membership. . . . The governing board and its employees, agents, consultants, and attorneys have absolute immunity from civil liability for communications, discussions, actions taken and reports made concerning disciplinary action or investigation taken or contemplated, if such reports or actions are made in good faith and without malice." Ind. Code § 16-10-1-6.5(b)

F. SPECIFIC ENUMERATION OF ANTI-COMPETITIVE EFFECTS IS NOT REQUIRED

It is impossible not to conclude that the legislature of the State of Indiana contemplates and requires medical peer review. Given the immunities and reporting requirements set forth in the statute, it is also indisputable that the Indiana legislature anticipated that some physicians would be in-

voluntarily removed from hospital staffs. The Petitioner contends that this does not constitute a "very specifically expressed state policy". Except for requiring that the legislature expressly state in the statute or legislative history that it intends that the required conduct have anticompetitive effect, it is hard to imagine how the legislature could have made its intent more specific, and it is quite difficult to believe that the Indiana legislature did not choose to use medical peer review for medical quality control over unregulated competition. This court has never accepted a requirement that the legislature specifically enumerate all anticipated effects expected and, indeed, has specifically rejected that as recently as two months ago. *Town of Hallie v. City of Eau Claire,* ____ U.S. ____, 82-1832 (1985), 53 L.W. 4418. This court specifically found that a requirement that the legislature catalog anticompetitive effects was unrealistic and might have deleterious consequences. The clear articulation requirement of the state action test is satisfied if the statutory provisions show that the legislature contemplated the kind of action complained of. Indiana has clearly done so here.

II.

THERE IS NO CONFLICT AMONG THE CIRCUITS REGARDING THE TEST USED BY THE SEVENTH CIRCUIT.

The Petitioners originally argued that there was a conflict among the circuits regarding whether compulsion was required before the court could find that there was a clearly and affirmatively expressed state policy. Since this court has recently ruled on that issue, that alleged conflict no longer remains.

Petitioners, originally cited two cases for another standard. They are *Capital Telephone Company v. New York Telephone Company,* 84-7176 (2nd Cir. 12/18/84) and *Hybud Equipment Corp. v. City of Akron,* 742 F. 2d 949 (6th Cir. 1984), cert. denied, (April 1, 1985). Both cases found that there was state action in the circumstances before them. The court in *Capital*

Telephone indicated that it was following the test set by this court in *California Retail Liquor Dealers Assn v. Midcal Aluminum, Inc.*, 445 U.S. 97, 63 L.Ed 233, 100 S.Ct. 937 (1980). The *Capital Telephone* court rejected the specificity requested by the plaintiff here and stated that activities that are reasonably necessary or related to the subject of the legislation should be included within the scope of the immunity. In *Hybud Equipment Corp. v. City of Akron*, 742 F. 2d 9494 (6th Cir. 1984), the court also upheld a determination of a clearly and affirmatively expressed state policy despite their inability to find a direct statutory provision for it. The court stated:

> "If the challenged anticompetitive restraint of a non-sovereign state representative, for which there is no express statutory provision, is necessary to carry out the representatives' mandate, then a legislative intent to displace competition may be inferred from the legislature's delegation of authority." Id at 960

Both of these cases adopted a broader standard than that used by the Seventh Circuit here. The Seventh Circuit in this case noted that there is a legislative requirement that hospitals and their medical staffs form peer review committees. Here there is specific statutory authority requiring the hospital and its medical staff to engage in peer review. There simply is no conflict demonstrated by these cases.

The *Amicus* brief cites the case of *Ratino v. Medical Service of the District of Columbia*, 718 F. 2d, 1260 (4th Cir. 1983) as being in conflict with the decision of the Seventh Circuit. Respondents believe that the intervenors have misread both cases. *Ratino* alleged a price fixing conspiracy. Blue Shield had an insurance plan which provided for payment of usual, customary and reasonable fees. When Blue Shield believed a fee was not reasonable, it referred that dispute to a fee review committee which was made up of physicians. One defense raised was that the conduct was exempt under the *Parker* doctrine. The Fourth Circuit examined the law of the

State of Maryland which provided for a commission on medical discipline. The commission was authorized to take certain disciplinary actions for enumerated causes including gross and wilful and continued overcharging for professional services. Apparently the commission could request committees of local medical societies to conduct investigations. However, under the facts of that case, the committee reviewing usual, customary and reasonable charges for Blue Shield was not one appointed by the commission on medical discipline. Further the court noted that the Maryland Statute did not provide for any medical committees to review or police physician charges. That case is substantially different from the case at issue herein. In fact all of these cases are consistent in the standards applied and differ because the nature and extent of the state's programs are factually dissimilar.

First, the Indiana legislature clearly has provided for quality review by hospital peer review committees. The Petitioners and Intervenors suggest, in effect, that a state legislature cannot choose to favor medical staff peer review for quality control purposes over the Sherman Antitrust Act. That is directly contrary to the theory of *Parker* and has been decided adversely to their position by this court many times.

The real task of the courts continues to be that they must review the state policy to see what it provides. The Fourth Circuit found that Maryland had not authorized physician committees to engage in price fixing. The state policy, here enacted by the legislature, must be reviewed to see if it meets standards established by this court. The states are and should be free from federal antitrust law if they adopt policies meeting the standards of this court which entitle them to that exemption. The Seventh Circuit reviewed Indiana's program, enacted directly by its legislature, and found that Indiana's statutes provided medical staff peer review for quality control.

3. THE STATE OF INDIANA ACTIVELY SUPERVISES THE MEDICAL PEER REVIEW PROCESS.

California Liquor Dealers v. Midcal Aluminum, 445 U.S. 97, 63 L.Ed. 2d 233, 100 S.Ct. 937 (1980) has given us the

basic test for the state action exemption relative to private parties. That case involved a private setting of prices for wine pursuant to California Statute. This court articulated the two requirements for antitrust immunity:

> "First, the challenged restraint must be 'one clearly articulated and affirmatively expressed as state policy'; Second, the policy must be 'actively supervised' by the state itself." Id. at 105

This court found that California's wine pricing programs satisfied the first standard, but because there were no standards for price fixing or review of the results thereafter, the court found that there was insufficient state involvement to allow the state action exemption for this price fixing arrangement. The courts of California had also refused to enforce it.

The State of Indiana has set forth a statutory, regulatory and judicial program of supervision and regulation. It has a strong and valid interest in protecting the health and welfare of its citizens, and its statutes and regulations demonstrate the extensive program adopted by the state to protect those interests.

Both physicians and hospitals must be licensed by Indiana before they can treat the public. Ind. Code § 25-22.5-2-1 et seq. and Ind. Code § 16-10-1-1 et seq. Pursuant to regulations adopted by the Indiana State Board of Health, the governing body of the hospital is required to approve rules and regulations of the medical staff (including audit procedures to assure quality of care) and to appoint the members of the medical staff and assign privileges. These must be made available and are subject to review by the State Board of Health. 410 IAC 15-1-1 et seq. As indicated previously, the State Board of Health is required to conduct inspections to be sure that the hospital is, in fact, complying with state regulations, including those involving peer review, in order to maintain its license.

Indirect administrative review is provided by the requirement that the hospital governing board report any adverse proceedings regarding medical staff privileges to the medical licensing board. Ind. Code § 16-10-1-6.5. The legislature of the State of Indiana has required hospitals to engage in peer review and has contemplated the removal of some physicians from hospital staffs. It has also provided for immunities subject to limited judicial review as set forth in Ind. Code § 34-4-12.6-1 et seq.

Hospitals are subject to sanctions for failure to comply with Indiana statutes and regulations. The hospital is required to have a fair hearing plan and peer review committees. The State of Indiana has provided review of the actual planning process by the Hospital Council and State Board of Health. They have an obligation to periodically inspect the hosptial and have the right to review specific proceedings which are required to be made available to them.

The State of Indiana has chosen to provide additional review, subject to statutory standards, through the courts of Indiana. Under Indiana procedure, Dr. Marrese was entitled to judicial review under the standards established. In fact, he challenged the peer review process in the state court which found that Dr. Marrese had not sustained his burden of proof in proving malice. The court further found that the proceedings were taken pursuant to the peer review provisions at issue herein. As indicated previously, Indiana provides immunity for participants in peer review proceedings for actions taken therein unless their actions are found not to be in good faith. Dr. Marrese has exhausted his appeals from the Indiana state action, though this occurred subsequent to the District Court's dismissal of the claimed antitrust cause of action.

Dr. Marrese's position is that the Medical Licensing Board, which receives the hospital's report of adverse actions taken against him, does not directly regulate the hospital's procedure and thus the state has no method of supervision. As indicated,

that is only a portion of the review provided by the State of Indiana in its regulation of peer review.

In Indiana, the legislature has chosen a level of review to insure due process and fair dealing for all physicians involved in the peer review process. It has also, however, determined that its policy of requiring peer review will be best served by the limited review found in the Indiana Code. The legislature has designated both administrative agencies and the courts as appropriate entities for reviewing the conduct of peer review committees under standards set by it. However, it is important to note that the Indiana legislature has made the policy decision to set both the standards and the forum for that review. Indiana has provided for limited judicial review for peer review committees and immunities for the participants in those committees. That clearly manifests the legislature's intent to have direct, but limited, review by the Indiana courts of any peer review proceeding. The program insures due process and avoids vidictive private proceedings. However, it also clearly manifests a state legislative policy preferring peer review to maintain medical quality. Indiana's legislature has recognized that the more generalized review called for by Dr. Maresse could result (and we believe would result) in substantial reluctance on the part of physicians and hospitals to engage in peer review. The legislature chose to provide immunity to participants in peer review, and chose limited judicial review.

The Seventh Circuit explained the Legislature's concern that the threat of extensive litigation, with its attendant financial burdens and potential liabilities, is onerous and would logically discourage peer review. The Indiana courts have followed Indiana's standards for review. *Yarnell v. Sisters of St. Francis Health Services,* 446 N.E. 2d 359 (Ind. App. 1983). Many courts have been conscious of the appropriateness of encouraging peer review. Indeed Congress has also required

medical peer review for quality control for those receiving federal funds through Medicare. A health care practitioner can be disqualified by an adverse decision of a private peer review contractor whose recommendation is automatically effective after 120 days unless the Secretary reverses it or, in some cases, a court does so. Congress also granted immunity for these peer review proceedings. *Peer Review Improvement Act of 1982,* P.L. 97-248, § 141-150.

Courts have recognized that imposing potential antitrust antitrust liability would significantly dampen the willingness of physicians to be involved in peer review. *Pontius v. Childrens Hospital,* 552 Fed. Supp. 1352 (W. D. Penn. 1982). This court, in a somewhat different context, has noted that a hospital has an unquestioned right to exercise control over the identity and number of doctors to whom it accords staff privileges pursuant to state law and regulation. *Jefferson Parish Hospital District No. 2 v. Hyde,* ____ U.S. ____, 80 L.Ed. 2d 2, 104 S.Ct., 1551 (1984). All of this is consistent with the decision of the Indiana Legislature to provide immunity and limited judicial review.

The case of *Bates v. State Bar of Arizona,* 443 U.S. 350, 53 L.Ed. 2d 810, 97 S. Ct., 2691 (1977) reinforces this court's review of the factors considered in applying the state action immunity to the professions. *Bates* involved advertising restraints by attorneys. Enforcement procedures were handled by a committee of the State Bar of Arizona. The plaintiffs therein argued that the state court immunity doctrine should not apply both because a private party was involved and because the limits prescribed by Arizona were "not tailored so as to intrude upon the federal interest to the minimum extent necessary." Id. at 361. This court rejected plaintiff's position on antitrust grounds and noted the state's substantial interest in the regulation of the activities of the bar. The case was eventually reversed on First Amendment grounds, but the state action immunity doctrine was found to be applicable.

Indiana has chosen to monitor the plans and process of peer review through administrative agencies, primarily, though not exclusively, through the Hospital Licensing Council and the

State Board of Health. It has further chosen to make available a judicial remedy for physicians whose staff privileges had been revoked when that revocation has been done with malice. This can be analogized to the admittedly adequate supervision discussed in *Southern Motor Carriers Rate Conference, Inc. v. United States,* ___ U.S. ____, 82-1922 (1985), 53 L.W. 4422. In that situation, private parties submitted proposed rates to the state agencies which became effective if the state agency took no action within a specified period of time. In this case, hospitals submit their plans for peer review to the state agencies as a requirement for maintaining their licenses. The state agency has the duty to review the policy set forth in the fair hearing plan. It also has the right to review the proceedings of any peer review panel. The Petitioner has the right to judicial review under standards set by the Indiana legislature as a protection against the misuse of peer review proceedings.

The Petitioners and Intervenors have taken the position that there should be discovery and an evidentiary hearing to determine whether state action applies. That contradicts the rationale behind the state action doctrine. As this court said in *Hoover v. Ronwin,* ____ U.S. ____, 80 L.Ed. 2d 590, 104 S.Ct. 1989 (1984):

> "The reasoning adopted by the dissent would allow Sherman Act plaintiffs to look behind the actions of state sovereigns and base their claims and perceived conspiracies to restrain trade among the committees, commissions or others who necessarily must advise the sovereign. Such a holding would emascuate the *Parker v. Brown* doctrine." Id. at 607.

Hoover involved involved the actions of a committee of the state bar examiners of the State of Arizona. The plaintiff therein alleged the same type of boycott as has Dr. Marrese, and the parallels regarding alleged motivation are similar. This court found the determinative issue to be whether there was state action as was originally articulated in *Parker v. Brown,* 317 U.S. 341, 87 L.Ed. 315, 63 S.Ct. 307 (1943).

If there is state action, the motivation of the participants is immaterial. It is immaterial because the State, here Indiana, has chosen to regulate and supervise this field which precludes antitrust review.

A fair reading of Dr. Marrese's complaint demonstrates that the basis for his lawsuit is his belief that peer review proceedings were instituted against him which resulted in his removal from the staff at Deaconess Hospital. His complaint alleges that Respondents acted in various ways that were improper, and that he should be entitled to an antitrust review of these proceedings. Indiana has chosen a different statutory program which puts a greater emphasis on the need to have quality review of health care professionals in order to protect the public. That is not the program that Dr. Marrese wants, but it is the program adopted by the legislature of the State of Indiana. There is nothing in the Sherman Antitrust Act indicating that the state could not and should not adopt such a program, and the courts continue to recognize the states' interest in regulating the professions in ways that they see fit. That is what Indiana has done.

Both the Petitioners and the Intervenors argue that there is a federal supremacy issue here. There is no question that, within its constitutional authority, Congress could choose to pass legislation which will void otherwise applicable state legislation. However, the supremacy argument asserted has been decided adversely to the Petitioners in *Parker v. Brown,* 317 U.S. 341, 87 L.Ed. 315, 63 S.Ct. 307 (1943). The question decided in *Parker* was whether the Congress intended to prohibit state governments from pursuing policies which may be inconsistent with the Sherman Antitrust Act. The *Parker* court found that Congress clearly did not have such an intent and that it would not be lightly inferred. In effect, the Petitioner and the Intervenors argue what has been termed by commentators as the exemption doctrine. Exemption requires an analysis of potential conflicts between two statutes of the same sovereign. The courts in that situation try to construe

statutes to avoid such a conflict, and the presumption is against an implied exemption from one of the statutes. Thus, the courts have relatively narrowly construed the many exemptions to the Sherman Antitrust Act enacted by Congress. These range from patents through insurance with many stops in between.

The preemption doctrine is significantly different. Preemption deals with enactments of two sovereigns, one federal and the other state. The inquiry for preemption is whether the federal government has exclusively occupied a particular field or whether federal law in that area is so flatly in conflict with state law that the two cannot coexist. *Handler, "Antitrust-1978",* 78 Columbia Law Review 1374 (1978). In exemption analysis, there is a presumption in favor of the antitrust laws and against any implied repeal. In preemption analysis, the presumption is in favor of state law and against the exercise of federal power. The *Parker* case clearly demonstrates the state action doctrine evolved out of a preemption analysis, and the court found that Congress did not intend to preempt state action. The Petitioner advances the supremacy argument because he recognizes that the Indiana legislature's provision for immunity of peer review committees would bar plaintiff's cause of action. Ind. Code § 34-4-12.6-1 et. seq.

The Intervenors claim that the opinion of the Seventh Circuit would in some way limit the ability of the States to regulate health care services and the licensing of physicians and hospitals. Obviously there is nothing in the state action doctrine which so limits the states. The state action doctrine reflects a decision by Congress and this court that the states are free to regulate activities without the constraint otherwise imposed by the Sherman Antitrust Act. The states, as sovereigns, are not constrained in any way by the state action doctrine. They would be substantially constrained if the Intervenors' position

were adopted because it, effectively, asks that the court not allow the states to choose medical peer review for quality control over antitrust concerns. The cite no authority for that proposition, because, since *Parker,* the issue has been closed.

CONCLUSION

Respondents respectfully submit that the Seventh Circuit's opinion in this case follows this court's two pronged test for determining whether state regulation of private parties is shielded from the antitrust laws. These are that the challenged restraint must be one clearly articulated and affirmatively expressed as state policy and that there must be active state supervision of its implementation. There is no conflict among the circuits on these tests, so that there is no necessity for this court's supervision. Wherefore, for the reasons discussed herein, the Respondents request that the court deny the Petition for Writ of Certiorari.

Respectfully Submitted,

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APPENDIX

INDIANA STATUTES AND REGULATIONS INVOLVED

(For convenience the sections cited by the Petitioners as well as those added by Respondents are contained herein.)

16-10-1-1 Power to license and regulate

Sec. 1. From and after the passage of this chapter the state board of health shall be empowered to license and regulate hospitals and ambulatory outpatient surgical centers. Such licensing and regulations shall be accomplished through a council to be created in the manner hereinafter provided, and such other employees as are hereinafter provided for.

16-10-1-2 Definitions

Sec. 2. The word "board" as used in this act, unless otherwise indicated, shall mean the state board of health. The word "council," unless otherwise indicated, shall mean the council herein provided for.

16-10-1-3 Council; members; appointment, qualifications, term, vacancies, chairman

Sec. 3. The council shall consist of eight (8) members, who shall be appointed by the governor within thirty (30) days after this act becomes effective, one of whom shall be a member of the medical profession having an unlimited license to practice medicine in the state of Indiana, one (1) of whom shall be a registered nurse, four (4) of whom shall be persons engaged in hospital administration. The two (2) remaining members shall be ex officio members, one (1) of whom shall be appointed by the governor from the state department of public welfare, and the other of whom shall be appointed from the state board of health. Of the original hospital administrators appointed one (1) shall serve for one (1) year, one (1) for two (2) years, one (1) for three (3) years and one (1) for four (4) years. The original members appointed from the medical

profession and the nursing profession shall serve for three (3) years. The members appointed from the department of welfare and board of health shall serve for two (2) years. All subsequent appointments shall be for four (4) years, except that in case of a vacancy the appointee shall serve for the remainder of the unexpired term. Any vacancy shall be filled from the same group as was represented by the outgoing member. The governor shall appoint a chairman and a chairman pro tempore.

16-10-1-6.5. Management of hospital—Appointment to medical staff—Medical staff—Medical review—Civil liability.—The governing board of the hospital shall be the supreme authority in the hospital, responsible for the management, operation, functioning and control of the hospital, and the appointment of the members of the medical staff and the assignment of privileges to members of the medical staff with the advice and recommendations of the medical staff consistent with their individual training, experience, and other qualifications. The medical staff of a hospital shall be an organized group which shall be responsible to the governing board for the clinical and scientific work of the hospital, advice regarding professional matters and policies to the governing board, and shall have the responsibility of reviewing the professional practices in the hospital for the purpose of reducing morbidity and mortality, and for the improvement of the care of patients in the hospital. This review shall include, but shall not be limited to, the quality and necessity of the care provided patients and the preventability of complications and deaths occurring in the hospital. The members of any medical staff committee organized for the purpose of conducting medical review, being retrospective and not a part of current patient care, shall have an absolute immunity from civil liability for communications made in committee meetings, and reports and recommendations made by the committee arising from deliberations by the committee to the governing board of the hospital or another duly authorized medical staff committee.

16-10-1-6.5 Governing board; disciplinary actions; reports; medical staff

Sec. 6.5. (a) The governing board of the hospital shall be the supreme authority in the hospital, responsible for the management, operation, functioning, and control of the hospital, and the appointment of the members of the medical staff and the assignment of privileges to members of the medical staff with the advice and recommendations of the medical staff consistent with their individual training, experience, and other qualifications.

(b) The governing board shall report, in writing, to the Indiana medical licensing board the results and circumstances of any final, substantive, and adverse disciplinary action taken by the governing board regarding a physician on the medical staff, or an applicant for the medical staff, if the action results in voluntary or involuntary resignation, termination, nonappointment, revocation, or significant reduction of clinical privileges or staff membership. Such a report shall not be made for nondisciplinary resignations nor for minor disciplinary action taken regarding physicians. The governing board and its employees, agents, consultants, and attorneys have absolute immunity from civil liability for communications, discussions, actions taken, and reports made concerning disciplinary action or investigation taken or contemplated, if such reports or actions are made in good faith and without malice.

(c) The medical staff of a hospital shall be an organized group which shall be responsible to the governing board for the clinical and scientific work of the hospital, advice regarding professional matters and policies to the governing board, and shall have the responsibility of reviewing the professional practices in the hospital for the purpose of reducing morbidity and mortality, and for the improvement of the care of patients in the hospital. This review shall include, but shall not be limited to, the quality and necessity of the care provided

patients and the preventability of complications and deaths occurring in the hospital.

(d) The members of any medical staff committee organized for the purpose of conducting medical review, being retrospective and not a part of current patient care, shall have an absolute immunity from civil liability for communications made in committee meetings, and reports and recommendations made by the committee arising from deliberations by the committee to the governing board of the hospital or another duly authorized medical staff committee.

16-10-1-7 Necessity of license; exemption of federal hospitals

Sec. 7. After January 1, 1946 no person, partnership, association, corporation, or any state, county or local governmental unit or any division, department, board or agency thereof shall establish, conduct, operate or maintain in the State of Indiana any hospital or ambulatory outpatient surgical center, as defined in this chapter, without having a license therefor as hereinafter provided. Hospitals operated by the federal government shall be exempt from the provisions of the chapter.

16-10-1-9 Application for license; requisites; procedures; issuance; renewal; fees

Sec. 9. Any person, partnership, association, corporation, or any state, county, or local governmental unit, or any division, department, board or agency thereof, in order to lawfully establish, conduct, operate, or maintain a hospital or an ambulatory outpatient surgical center in this state, shall obtain a license therefor from the board, upon the approval and recommendation of the council in the following manner:

(a) The applicant shall submit an application on a form to be prepared by the council with the approval of the state board of health, showing that the applicant is of reputable and

responsible character and able to comply with the minimum standards for a hospital or an ambulatory outpatient surgical center and with rules lawfully promulgated under this chapter. The application must contain the following additional information:

(1) the name of the applicant;

(2) the type of institution to be operated;

(3) the location of the institution;

(4) the name of the person to be in charge thereof; and

(5) such other information as the council, with the approval of the board, may require.

(b) The application must be accompanied by a licensing fee computed at the rate of four dollars ($4) per available hospital bed.

(c) The council may recommend and approve the issuance of a license upon the application without further evidence, or, in its discretion, it may have a hearing on the application and conduct its own investigation, to determine whether a license ought to be granted.

(d) If, after hearing, the council finds that a license should not be granted it shall so notify the applicant. The decision of the council shall be final.

(e) If, after hearing, the council finds that the applicant complies and will in the future comply with the provisions of this chapter and the rules promulgated under this chapter, then the council shall recommend and approve the issuance of a license, and thereupon a license shall be issued by the board licensing the applicant to operate the hospital or ambulatory outpatient surgical center for one (1) year.

(f) A license to operate a hospital or ambulatory outpatient surgical center shall expire one (1) year after the date

of issuance. It shall not be assignable or transferable, shall be issued only for the premises named in the application, and shall be posted in a conspicuous place in the facility. It may be renewed from year to year, upon the payment of a renewal fee computed at the rate of four dollars ($4) per available hospital bed.

16-10-1-10 Suspension or revocation of license

Sec. 10. The board may suspend or revoke a license issued hereunder on the recommendation of the council on any of the following grounds:

(a) Violation of any of the provisions of this chapter or of the rules and regulations issued pursuant hereto;

(b) Permitting, aiding, or abetting the commission of any illegal act in such institution; or

(c) Conduct or practice found by the council to be detrimental to the welfare of the patients of such institution.

The procedure governing the suspension or revocation of any license shall be as follows:

(1) A complaint shall be filed by the board stating facts constituting a ground or grounds for revocation or suspension.

(2) The licensee shall be given notice of not less than thirty (30) days of the time and place for a hearing before the council on said complaint, which notice shall be sent by registered mail to the licensee at the address shown in his application. The licensee shall be entitled to be represented by legal counsel at said hearing.

(3) The council may recommend to the board after such hearing either that the license be suspended or that it be revoked.

(4) If the council recommends suspension of a license it may also recommend the conditions to be met by the licensee

during the period of suspension in order to entitle the licensee to resume operation of the said hospital or ambulatory outpatient surgical center on the existing license.

(5) If the council recommends either suspension or revocation the board shall, pursuant thereto, enter an order in accordance therewith in which order shall be set forth the grounds of such suspension or revocation.

(6) The council may, in its discretion, after hearing, hold the case under advisement and make a recommendation to the board as to requirements to be met by said licensee in order to avoid either suspension or revocation; and in such cases the board shall enter an order accordingly and notify the licensee thereof by registered mail. Then if the licensee complies with such order and proves that fact to the satisfaction of the council, the council shall recommend to the board that an order be entered showing satisfactory compliance and dismissing the case because of such compliance, and the board shall enter such an order.

16-10-1-11 Appeals

Sec. 11. Any licensee, or applicant for a license, aggrieved by the action of the council and the board may appeal from such action to the circuit or superior court of the county in which the hospital or ambulatory outpatient surgical center in question is located, or is proposed to be located, by filing a notice and bond in the amount of two hundred dollars ($200) for the payment of costs, in the office of the county clerk of such county, who shall thereupon notify the board that such appeal has been taken. The board shall thereupon cause to be certified to such court a copy of the complaint and of the recommendation of the council and the order of the board in cases of suspension or revocation; or of the application and order of refusal of a license, in any case where a license was refused. The case shall then be docketed as a civil action, with the

applicant or licensee as the plaintiff and the board as the defendant. No further pleading shall be necessary. Such court shall have jurisdiction to the extent that courts exercise jurisdiction over administrative bodies and may enter an order either sustaining the action of the board and council or setting it aside. The clerk of such court shall certify to the board a copy of the decision of such court. An appeal may be had from the decision of such court.

16-10-1-12 Rules and regulations for operation and management of hospital; minimum standards for equipment and patient care

Sec. 12. The council shall have the duty and power to adopt such rules and regulations pertaining to the operation and management of hospitals and ambulatory outpatient surgical centers, and to rescind, amend, or modify such rules and regulations from time to time, as are necessary in the public interest and particularly for the establishment and maintenance of standards of hospitalization required for the efficient care of patients. It shall prescribe, by rules and regulations adopted by it, the minimum standards as to equipment and provision for the care of patients to which an institution must conform in order to operate lawfully as a hospital or as an ambulatory outpatient surgical center.

16-10-1-13 Inspection; exemption from laws relating to hotels, restaurants, etc.

Sec. 13. Every hospital or ambulatory outpatient surgical center, as defined in this chapter, for which a license has been issued, shall be inspected periodically by a duly appointed representative of the board under the rules and regulations to be promulgated under this chapter. Inspection reports shall be prepared on forms prescribed by said council. No institutions or agencies licensed pursuant to the provisions of this chapter shall be required to be inspected or licensed under the laws of

this state relative to hotels, restaurants, lodging-houses, boarding-houses and places of refreshment.

16-10-1-14 Rules and regulations; approval

Sec. 14. All rules and regulations to become effective shall be jointly approved by the council and the board, and promulgated in the manner provided by law for the promulgation of rules and regulations of administrative bodies.

16-10-1-17 Administrative and clerical employees; inspections

Sec. 17. The board is authorized to employ all necessary administrative and clerical employees; and to employ one (1) or more inspectors for such time as in the judgment of the board and council may be necessary, who shall be well experienced in the operation of hospitals, and whose duty it shall be, (a) to visit all institutions coming under the scope of this act, and inspect them in so far as it may be necessary to arrive at the necessary facts required to make a true and informative report to the said council; and, (b) to give advice, aid, and encouragement to such institutions, in maintaining high professional ideals and good care of patients.

25-22.5-2.1. Creation and membership—The medical licensing board of Indiana is created. It shall consist of seven [7] members, not more than four [4] of whom shall be members of the same political party. The members shall be appointed by the governor, and all vacancies occurring on the board shall be filled by the governor. The membership of the board shall consist of:

(1) Five [5] reputable physicians who are graduates of a medical school who hold the degree of doctor of medicine or its equivalent and who hold valid unlimited licenses to practice medicine in Indiana, and who shall serve for terms of four [4] years each;

(2) One [1] reputable osteopathic physician who is a graduate of an accredited osteopathic medical school who holds

the degree of doctor of osteopathy or its equivalent and who holds a valid unlimited license to practice osteopathic medicine in Indiana, who shall serve for a term of four [4] years; and

(3) One [1] member to represent the general public who is a resident of this state and in no way associated with the medical profession other than as a consumer.

25-22.5-2-7. Powers and duties.—The board shall:

(a) Promulgate rules, regulations and forms necessary to implement this article. It may adopt rules and regulations concerning, but not limited to, the following areas:

(i) Qualification by education, residence, citizenship, training and character for admission to an examination for licensure or by endorsement for licensure;

(ii) the examination for licensure itself;

(iii) the license or permit itself;

(iv) Fees for examination, permit, licensure, and registration; and

(v) Reinstatement of licenses and permits;

(b) Administer oaths in matters relating to the discharge of their official duties;

(c) Enforce this article, and assign service bureau personnel duties, as may be necessary in the discharge of the board's duty;

(d) Maintain, through the service bureau, full and complete records of all applicants for licensure or permit and of all licenses and permits issued;

(e) Make available, upon request, the complete schedule of minimum requirements for licensure or permit;

(f) Have the power to issue a temporary permit to an applicant for the interim from the date of application until the next regular meeting of the board;

(g) Have the duty to issue an unlimited license, a limited license or a permit, depending upon the qualifications of the applicant, to any applicant who successfully fulfills all of the requirements of this article; and

(h) Adopt rules establishing standards for the competent practice of medicine or osteopathic medicine, or any other form of practice regulated by a limited license or permit issued under this article.

25-22.5-3-1. Minimum requirements.—The minimum requirements for all applicants for an unlimited license to practice medicine or osteopathic medicine in Indiana must include but are not limited to the following:

(a) [Repealed.]

(b) The applicant must not have a conviction for an act which would constitute a ground for disciplinary sanction under IC 25-22.5-6-2.1(b).

(c) The applicant shall possess the degree of doctor of medicine or doctor of osteopathy or its equivalent from a medical school which was approved by the board as of the time the degree was conferred.

(d) The applicant shall have successfully passed the examination for licensure or shall have satisfied the requirements for licensure by endorsement as prescribed by the board.

(e) The applicant shall be physically and mentally capable of safely engaging in the practice of medicine or osteopathic medicine and shall submit to an examination if deemed necessary by the board to determine such capability.

(f) [Repealed.]

(g) the applicant shall not have had his license previously revoked or suspended by the board or by the licensing agency of any other state by reasons of his inability to safely practice medicine or osteopathic medicine, and those reasons are still valid in the opinion of the board.

(h) The applicant shall have submitted a complete transcript of his educational records, grades and diploma from his medical school with an English translation thereof.

(i) The applicant shall, at the board's discretion, make a personal appearance before it.

25-22.5-6-2.1. Disciplinary sanctions.—(a) As used in this section and section 3[25-22.5-6-3] of this chapter, "practitioner" means an individual who holds an unlimited license, limited license, or permit issued under this article.

(b) A practitioner shall conduct his practice in accordance with the standards established by the board under IC 25-22.5-2-7(h) and is subject to the exercise of the disciplinary sanctions under subsection(e) if, after a hearing, the board finds:

(1) The practitioner has employed or knowingly cooperated in fraud or material deception in order to obtain a license to practice, or has engaged in fraud or material deception in the course of professional services or activities, or has advertised services in a false or misleading manner;

(2) The practitioner has been convicted of a crime which has a direct bearing on the practitioner's ability to continue to practice competently;

(3) A practitioner has knowingly violated any rule adopted by the board under IC 25-22.5-2-7(h);

(4) A practitioner has continued to practice although he has become unfit to practice due to:

(A) Professional incompetence;

(B) Failure to keep abreast of current professional theory or practice;

(C) Physical or mental disability; or

(D) Addiction or severe dependency upon alcohol or other drugs which endangers the public by impairing a practitioner's ability to practice safely;

(5) A practitioner has engaged in a course of lewd or immoral conduct in connection with the delivery of services to patients;

(6) A practitioner has allowed his name or license issued to him under this chapter to be used in connection with any individual who renders services beyond the scope of his training, experience, or competence.[;]

(7) A practitioner, except as otherwise provided by law, has knowingly prescribed, sold, or administered any drug classified as a narcotic, addicting, or dangerous drug to a habitue or addict; or

(8) A practitioner has had a license to practice in another state revoked or suspended by that state on grounds similar to those under this section: A certified copy of the record of suspension or revocation is conclusive evidence of the other state's suspension or revocation.

(c) The board may order a practitioner to submit to a reasonable physical or mental examination if his physical or mental capacity to practice safely is at issue in a disciplinary proceeding.

(d) Failure to comply with a board order to submit to a physical or mental examination shall render a practitioner liable to the summary revocation procedures under subsection (f) [of this section].

(e) The board may impose any of the following sanctions, singly or in combination, when it finds that a practitioner is guilty of any offense under subsection (b) [of this section]:

(1) Permanently revoke a practitioner's license;

(2) Suspend a practitioner's license;

(3) Censure a practitioner;

(4) Issue a letter or reprimand; or

(5) Place a practitioner on probation status and require the practitioner to:

(A) Report regularly to the board upon the matters which are the basis of probation;

(B) Limit practice to those areas prescribed by the board; or

(C) Continue or renew professional education under a preceptor approved by the board until satisfactory degree of skill has been attained in those areas which are the basis of the probation.

The board may withdraw the probation if it finds that the deficiency which required disciplinary action has been remedied.

(f) The board may summarily suspend a practitioner's license for a period of ninety [90] days in advance of a final adjudication or during the appeals process if the board finds that a practitioner represents a clear and immediate danger to the public health and safety if he is allowed to continue to practice. The summary suspension may be renewed upon a hearing before the board, and each renewal may be for a period of ninety [90] days or less.

(g) The board may reinstate a license which has been suspended under this chapter if, after a hearing, the board is satisfied that the applicant is able to practice with reasonable skill and safety to patients. As a condition of reinstatement, the board may impose disciplinary or corrective measures authorized under this chapter.

(h) The board shall seek to achieve consistency in the application of the sanctions authorized in this section, and significant departures from prior decisions involving similar conduct shall be explained in the board's findings or orders.

25-22.5-6-3 Disciplinary proceedings

Sec. 3. Disciplinary Proceedings. (a) Proceedings for the probation of a licensee or a permit holder or the revocation or

suspension of any license or permit to practice medicine or osteopathic medicine in Indiana must be commenced by the filing of written verified charges with the secretary of the board. These charges may be filed by any resident of Indiana, or by the secretary or any member of the board upon information from whatever source in his possession, which causes the member to have reasonable cause to believe that the matter should be filed and placed before the board for its determination. Proceedings for probation of a licensee or permit holder or revocation or suspension of any license or permit to practice medicine or osteopathic medicine in Indiana must be conducted according to the administrative adjudication act of Indiana, IC 4-22-1. Approval by a majority of all members of the board shall be required for any action to be taken.

(b) Any person who files charges or testifies before the board in any disciplinary proceeding is immune from civil liability for damages for any sworn or written testimony made with probable cause and without malice.

(c) The administrator, his staff, counsel, investigators, hearing officers, and the board members are immune from civil liability for damages for conduct within the scope and arising out of the performance of their duties.

34-4-12.6-1. Definitions.—(a) As used in this chapter, "professional health care provider" means:

(1) A physician licensed under IC 25-22.5;

(2) A dentist licensed under IC 25-14;

(3) A hospital licensed under IC 16-10-1;

(4) A podiatrist licensed under IC 25-29;

(5) A chiropractor licensed under IC 25-10;

(6) An optometrist licensed under IC 25-24;

(7) A psychologist licensed under IC 25-33;

(8) A pharmacist licensed under IC 25-26;

(9) A health facility licensed under IC 16-10-4;

(10) A registered or licensed practical nurse licensed under IC 25-23;

(11) A physical therapist licensed under IC 25-27; or

(12) A home health agency licensed under IC 16-10-2.5.

(b) As used in this chapter, "evaluation of patient care" relates to:

(1) The accuracy of diagnosis;

(2) The propriety, appropriateness, or necessity of care rendered by a professional health care provider; and

(3) The reasonableness of the utilization of services, procedures and facilities in the treatment of individual patients.

As used in this chapter, the term does not relate to charges for services nor to methods used in arriving at diagnoses.

(c) As used in this chapter, "peer review committee" means a committee having the responsibility of evaluation of qualifications of professional health care providers, or of patient care rendered by professional health care providers, or of the merits of a complaint against a professional health care provider that includes a determination or recommendation concerning the complaint. The committee must meet the following criteria:

(1) The committee is organized:

(A) By a state, regional, or local organization of professional health care providers or by a not-for-profit foundation created by such a professional organization for purposes of improvement of patient care;

(B) By the professional staff of a hospital or other health care facility;

(C) By state or federal law or regulation; or

(D) As a governing board of a hospital or professional health care organization.

(2) A majority of the members of the committee are professional health care providers holding licenses in the stated profession of the committee, or the governing board of a hospital or professional health care organization. However, "peer review committee" does not include a medical review panel created under IC 16-9.5-9.1.

(d) As used in this chapter, "professional staff" means all professional health care providers holding licenses in a single profession, authorized to provide health care in a hospital or other health care facility.

(e) As used in this chapter, "personnel of a peer review committee" means not only members of the committee but also all of the committee's employees, representatives, agents, attorneys, investigators, assistants, clerks, staff, and any other person or organization who serves a peer review committee in any capacity.

(f) As used in this chapter, "in good faith" refers to an act taken without malice after a reasonable effort to obtain the facts of the matter and in the reasonable belief that the action taken is warranted by the facts known. In all actions to which this chapter applies, good faith shall be presumed; and malice shall be required to be proven by the person aggrieved.

(g) As used in this chapter, "professional health care organization" means an organization composed of professional health care providers.

34-4-12.6-2. Confidentiality and privilege.—(a) All proceedings of a peer review committee shall be confidential, and all communications to a peer review committee shall be privileged communications to the peer review committee. Neither

the personnel of a peer review committee nor any participant in a proceeding therein shall reveal any content of communications to, or the records or determination of, a peer review committee outside the peer committee. However, the governing board of a hospital or professional health care organization may disclose the final action taken with regard to a professional health care provider without violating the provisions of this section. Except as otherwise provided in this chapter, no person who was in attendance at any such peer review committee proceeding shall be permitted or required to disclose any information acquired in connection with or in the course of such proceeding, or to disclose any opinion, recommendation, or evaluation of the committee or of any member thereof. Information otherwise discoverable or admissible from original sources is not to be construed as immune from discovery or use in any proceeding merely because it was presented during proceedings before such peer review committee, nor is a member, employee, or agent of such committee or other person appearing before it to be prevented from testifying as to matters within his knowledge and in accordance with the other provisions of this chapter, but the witness cannot be questioned about this testimony or other proceedings before such committee or about opinions formed by him as a result of committee hearings.

(b) Any professional health care provider under investigation shall be permitted at any time to see any records accumulated by a peer review committee pertaining to his personal practice and shall be offered the opportunity to appear before the peer review committee with adequate representation to hear all charges and findings concerning his practice and to offer rebuttal information, which shall be a part of the record before any disclosure of the charges and findings under this chapter. However, a professional health care provider under investigation in a hospital is entitled to only one [1] evidentiary hearing before a peer review committee of the medical staff and

one [1] additional hearing on appeal before the governing board of the hospital. Communications to, and the records and determinations of, a peer review committee may only be disclosed to the peer review committee of a hospital or other health facility, the disciplinary authority of the professional organization of which the professional health care provider under question is a member, or the appropriate state board of registration and licensure which the committee considers necessary for recommended disciplinary action, and shall otherwise be kept confidential for use only within the scope of the committee's work.

(c) Except in cases of required disclosure as authorized in this chapter, no records or determinations of, or communications to, a peer review committee shall be:

(1) Subject to subpoena or discovery; or

(2) Admissible in evidence;

in any judicial or administrative proceeding, including a proceeding under IC 16-9.5-10, without a prior waiver executed by the committee. Except in cases as authorized in this chapter, the evidentiary privileges created by this section shall be invoked by all witnesses and organizations in all judicial and administrative proceedings unless the witness or organization first has a waiver of the privilege executed in writing, on behalf of the peer review committee holding the privilege, by its chairman, vice chairman, or secretary.

(d) The immunities granted by section 3 [34-4-12.6-3] of this chapter shall not extend to any person who violates the confidentiality requirements of this section.

34-4-12.6-3. Immunity.—(a) There shall be no liability on the part of, and no action of any nature shall arise against, the personnel of a peer review committee for any act, statement made in the confines of the committee, or proceeding thereof made in good faith in regard to evaluation of patient care as

that term is defined and limited in section 1(b) [34-4-12.6-1(b)] of this chapter.

(b) Persons or organizations, including peer review committees, who, in good faith, furnish records, information or assistance to a peer review committee, in regard to evaluation of qualifications of professional health care providers, or of patient care as that term is defined and limited in section 1(b) of this chapter, shall be immune from any civil action arising from such acts.

(c) The personnel of a peer review committee shall be immune from any civil action arising from any determination made in good faith in regard to evaluation of patient care as that term is defined and limited in section 1(b) of this chapter.

(d) No restraining order or injunction shall be issued against a peer review committee or any of the personnel thereof to interfere with the proper functions of the committee acting in good faith in regard to evaluation of patient care as that term is defined and limited in section 1(b) of this chapter.

34-4-12.6-4. Use of information obtained by peer review committees.—A professional health care provider, a peer review committee, and the governing board of a hospital or professional health care organization may use information obtained by peer review committees for legitimate internal business purposes, including their own defense.

410 IAC 15-1-1 Definitions

Authority: IC 16-10-1-12; IC 16-10-1-14
Affected: IC 16-10-1-5

Sec. 1. DEFINITIONS. Unless otherwise provided for in the Law [*IC 16-10-1*], the following definitions shall control:

(1) Board—Indiana State Board of Health.

(2) Council—Hospital Licensing Council.

(3) Hospital—A facility that provides continuous and uninterrupted service to inpatients under the supervision of physicians, which is classified as such by the Council and the Board in accordance with the definition contained in IC 1971, 16-10-1-6. Any patient care establishment (excluding mental institutions) caring for patients for more than twenty-four (24) hours which provides on the premises one (1) or more of the specialized services of X-ray, laboratory, pharmacy, or other technical services requiring professionally-trained personnel in attendance shall be considered as functioning as a hospital. Hospital units of any type which operate only a portion of the year may be considered as providing continuous services for the population group served and must have a firm commitment with a local hospital for transfer of patients.

(4) General Hospital—A hospital which provides hospitalization which is not limited to specific diseases, conditions, or age groups. Maternity care may or may not be provided.

(5) Specialized Hospital—Any hospital which provides hospitalization limited to a specified disease(s), condition, or age group.

(6) Hospitalization—The reception and care of any person for the purpose of giving advice, diagnosis, or treatment bearing primarily on the physical health of such persons and maternity care involving labor and delivery for any period of time.

(7) Medical Staff—The organized body of individuals holding appointments by the Governing Body of the hospital to membership on the Medical Staff of the hospital.

(8) Governing Body—The Governing Board, Board of Trustees or the owner or the person(s) designated by the owner as the governing authority.

(9) Physician—Any person holding an unlimited license to practice medicine or osteopathy, including surgery and obstetrics, in Indiana.

(10) Dentist—Any person holding an unlimited license to practice dentistry in Indiana.

410 IAC 15-1-2 Compliance with regulations; exceptions

Authority: IC 16-10-1-12; IC 16-10-1-14
Affected: IC 16-10-1

Sec. 2. COMPLIANCE WITH REGULATIONS. All hospitals shall comply with all regulations set forth herein, except those concerned with clinical services not provided in the hospital. Any situation that may arise which prevents a hospital from complying with any applicable regulation shall be reported to the Council. The Council may, upon written request, permit continuation of operation for a specified period of time, provided compliance with regulations is not immediately attainable and the safety and well-being of patients will not be jeopardized. In event of flood, fire, or other disaster, the Governing Body shall close all or part of the facility as may be necessary to insure the safety and well-being of patients until the Board approves reopening.

410 IAC 15-1-5 Governing body; powers and duties

Authority: IC 16-10-1-12; IC 16-10-1-14
Affected: IC 16-10-1-6.5; IC 16-10-1-9

Sec. 5. THE GOVERNING BODY. The governing board of the hospital shall be the supreme authority in the hospital, responsible for the management, operation, functioning, and control of the hospital. The Governing Body shall:

(a) File an application for licensure with the Board each year. Initial applications must be accompanied by documentation proving that the facility is legally organized and able and willing to meet hospital licensing regulations.

Reapplication must be filed during the year if there is a change in ownership. Written notification within thirty (30) days is to be made to the Board if there is a change in normal bed capacity as required in Item 10.6(e)(1)(b) [*410 IAC 15-1-10(6)(e)(1)(b)*], or change in clinical services other than those for which the license was issued. Current copies of organizational documents shall be available for inspection and forwarded to the Board upon request.

(b) Adopt bylaws and function accordingly.

(c) Have available for its use and for its administrator a written set of current (reviewed within the last two (2) years) goals and policies, long-range plans, and future goals and programs of the hospital.

(d) Employ an administrator with qualifications as set forth in Item 6.1 [*410 IAC 1-6(1)*] as the chief executive officer who is the liaison officer of the governing body to the Medical Staff.

(e) Define the responsibility and authority of the hospital administrator. Total responsibility and authority for management shall rest with the hospital administrator.

(f) Make provisions for an adequate budget for the hospital in order to meet the needs of patients.

(g) Approve the bylaws, rules, and regulations of the Medical Staff and audit procedures of other measures used to assure quality of care.

(h) Appoint members of the Medical Staff and assign privileges consistent with their individual training, experience, and other qualifications on a periodic basis (at least every two (2) years) with the advice and recommendations of the organized Medical Staff.

(i) Maintain liaison with the Medical Staff, preferably by an Advisory Committee with representation from the governing body, Medical Staff, and administration.

(j) Provide for a licensed physician to be on duty or on call at all times for in-house and emergency room call and available within fifteen (15) or twenty (20) minutes.

(k) Provide for close relationship with the community and its various health and welfare agencies.

(l) Provide for the administrator to attend meetings of the governing body and its committees.

(m) Designate the administrator or his designee as the Governing Body's representative for Medical Staff meetings.

(n) Review at least annually reports of operation, including patient services provided and results attained.

(o) Provide a physical plant that meets statutory requirements and provisions of these regulations.

(p) Space and equipment shall be provided for administrative and business offices, private admitting area, public lobby and toilets, personnel toilet and locker facilities, meeting or multipurpose rooms, and medical record facilities.

410 IAC 15-1-7 Medical staff; powers and duties

Authority: IC 16-10-1-12; IC 16-10-1-14
Affected: IC 16-10-1-6.5

Sec. 7. THE MEDICAL STAFF. (1) The Medical Staff of a hospital composed of two (2) or more physicians shall be an organized group which shall be responsible to the governing board for the clinical and scientific work of the hospital, advise regarding professional matters and policies to the governing board, or the board's designee, and shall have the responsibility of reviewing the professional practices in the hospital for the purpose of reducing morbidity and mortality, and for the improvement of the care of patients in the hospital. This review shall include, but shall not be limited to, the quality and

necessity of the care provided patients and the preventability of complications and deaths occurring in the hospital.

(2) The medical staff shall initiate and, with the approval of the Governing Body, adopt and periodically amend bylaws, rules, regulations, and policies which shall include, but need not be limited to, provisions for:

(a) Qualifications to be met for appointment to staff membership and for delineation of privileges.

(b) Assignment of staff members to active, consulting, or other staff group(s) which may be established.

(c) Designation of a chief or chairman of staff and chief of each department or service which may be established.

(d) Establishment of mechanism to carry out Medical Staff functions either by the staff as a whole or by designated committees in the following areas:

(1) Review of applications for staff membership delineation of privileges, and recommendations on appointment to the Governing Body.

(2) Appeal of decisions regarding Medical Staff membership and privileges.

(3) Review and analysis, at regular stated intervals, of clinical performance, pathological reports, the completeness of medical records and of the enforcement of requirements related thereto, of infection control, of use of blood and blood-related elements, and of total patient care.

(4) Participate in the established means of liaison with the Governing Body.

(e) Meetings of the staff as a whole or by department (when staff is well departmentalized) on a monthly basis.

(f) Maintenance of records on all meetings of the staff and committees thereof; however, these minutes shall be considered confidential.

(g) Consultation between physicians in cases when the diagnosis is obscure, or the best therapeutic measures are in doubt is required as part of the bylaws of the Medical Staff.

(3) Current constitution, bylaws, rules, and regulations adopted shall be made available for inspection and forwarded to the Board upon request.

410 IAC 15-1-8 Recordkeeping requirements

Authority: IC 16-10-1-12; IC 16-10-1-14
Affected: IC 16-10-1-13

Sec. 8. DOCUMENTS, REPORTS AND RECORDS. (1) Documents and records which show ownership and compliance with local, state and federal laws and regulations and adherence to bylaws and regulations of the facility shall be maintained within the hospital and shall be made available for examination by duly authorized representatives of the Council and the Board of Health. Items to be maintained are:

(a) Certified copy of Articles of Incorporation (not required of governmental hospitals or individual ownership).

(b) Constitutions, bylaws, and regulations of Governing Body and Medical Staff (signed and dated).

(c) Minutes of meetings of both the Governing Body, Medical Staff, and their committees thereof; such minutes shall be considered confidential.

(d) A current roster of members of Medical Staff and their designated privileges.

(e) A completed application for each member of the Medical Staff which includes the following data: Date of application, professional education and training by school and year, date of licensure, and number thereof in Indiana, Drug Enforcement Administration number, experience in the practice of medicine, type of Medical Staff appointment

and delineation of privileges desired, Medicaid provider number, if one is assigned, pledge to abide by rules and regulations of the hospital, and other items specified by the hospital and its Medical Staff.

(f) The current Indiana licensure or certification number (and serial number if issued) issued by the applicable official agency for physicians, dentists, pharmacists, nurses, physical therapists, and others as required.

(g) Personnel records for each employee of the facility which include personal data, education and experience, evidence of participation in job-related educational activities, and records of employees which relate to pre-employment and subsequent physical examinations, immunizations and chest X-rays and tuberculin tests.

(h) Pharmacy permit when required by Indiana Board of Pharmacy.

(i) Transfer agreements with nursing homes and other hospitals where indicated.

(2) Hospital Records of Patients

(a) Each hospital shall keep a record of all admissions, deaths, surgical records, outpatient records, deliveries, births, and stillbirths which give patient identification data, attending physician, results, and such pertinent data as is deemed needed by the hospital. Computerized records that maintain confidentiality are acceptable.

(3) Reports to State Board of Health

(a) Reports on the hospital and its operation shall be submitted on forms provided as specified by the Council.

(b) Reports of cases of disease shall be submitted as required by state communicable disease and tuberculosis laws and regulations.

844 IAC 4-6-1 Mandatory registration; time

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 1. Mandatory registration: time. Every physician holding a license issued by the Medical Licensing Board of Indiana shall register with the Board on or before July the 1st, biennially, with the exception that no registration or fee for registration is required of any licensee on or before the month of July of the year following the year within which his license was issued.

844 IAC 4-6-2 Mandatory registration; notice

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 2. Mandatory registration: notice. On or before June the 15th, biennially, the Medical Licensing Board of Indiana, or its duly authorized agent, shall notify each licensee that he is required to register with the Board. The Board, or its agent, shall furnish each licensee a form to be completed for registration.

844 IAC 4-6-3 Mandatory registration; oath

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 3. Mandatory registration: oath. Applications for initial registration must be made under oath.

844 IAC 4-6-4 Mandatory registration; fees

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5-7

Sec. 4. Mandatory registration: fees. Each licensee shall submit a fee as determined by the Board for each year or fraction thereof, in the form of a certified check, cashers check or postal money order and payable to the order of the Medical Licensing Board of Indiana.

844 IAC 4-6-5 Mandatory registration; delinquent registration

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 5. Mandatory registration: delinquent registration. In the event any licensee fails to submit his certificate of registration on or before September the 1st of every other year, he shall be required to pay a penalty fee in the amount of $20.00, in addition to the regular registration fee.

844 IAC 4-6-6 Mandatory registration; failure to register

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 6. Mandatory registration: failure to register. Upon the failure of any licensee to register with the Board by September the 1st of each biennium, the Board shall forthwith enter an order suspending the physician's license to practice medicine in the State of Indiana. Such order shall become effective ten (10) days from the entry thereof. A copy, thereof, shall be served upon the licensee by certified mail at the last address registered with the Board.

844 IAC 4-6-7 Practice after suspension

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 7. Practice after suspension. No physician shall engage in the practice of medicine in Indiana after the effective date of the order suspending his license to practice.

844 IAC 4-6-8 Reinstatement of physician to practice

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 8. Reinstatement of physician to practice. Every physician who has become delinquent in registration may be reinstated to practice by supplying the information requested by

the Board and paying a delinquent registration fee for the time accrued. The delinquent penalty fee shall be the sum of $20.00, in addition to the regular registration fee.

844 IAC 4-6-9 Inactive status

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 9. Inactive status. Any physician who has retired from practice and wants to retain his license may do so for half of the usual registration fee as given in Rule 2 844 IAC 4-2-1, provided that he does not maintain an office for the practice of medicine and does not charge for any medical services that he might render. A physician whose license is inactive may submit a written request to the Board to reactivate his license by paying the full registration fee.

844 IAC 4-6-10 Probation, suspension, or revocation

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 10. Probation, suspension, or revocation. The willful performance of an act likely to deceive or harm the public shall include, but not be limited to the following acts:

(1) Aiding and abetting a person to practice medicine without a license;

(2) Presigning of prescriptions;

(3) Prescribing or administering a drug for other than generally accepted therapeutic purposes;

(4) Gross negligence in the practice of medicine;

(5) False, deceptive, or misleading advertising;

(6) Fraudulent practice of billing a patient or third party payer for services not rendered.